

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13167



3 - OUTPATIENT

000001

9-10-98

pt comes to office c/o "bad H/A"

BP $\frac{220}{130}$ (R) 5^{min} post procordia $\frac{170}{110}$ (L) $\frac{170}{110}$ (R)

P 20 min post procordia $\frac{150}{86}$

Per Dr. [REDACTED] 1000mg Tylenol now - then
give $\frac{1}{2}$ Vicoprofen (pt. to take $\frac{1}{2}$ her)
when she gets home. (PT. driving).

Bp elevated and pt is c/o of ha....denies blurred vision or n.v..
VS stable and pt given Procordia and responded well....able to drive
home and continue present bp, eds....
HEENT. Neck supple PERLA FUNDWN WNL, neg exudates or hemorrhages or exudates
or av nicking noted. Neg JVD or bruits.
Hrr s murmurs neg s3 s4 clicks rubs or heaves.
Lungs CAT Neg rrs
Abd soft Bs all quads nomasses or bruits noted.
NEURO: CN 2- 12 grossly intact DTR's 2/4 brisk flat.
Extreme: Neg edema or cyanosis ~~no~~ clubbing noted.
PSYCH: Ox 3 good spirits and calm after visit.

A: 1. Hypertension uncontrolled
2. Hypothyroidism New onset.
3. Obesity.

PLAN. 1. Home rest and continue present meds and recheck with my office
in the am...
2. to ER if p~~ro~~blems should arise during the night....
3. Call if any questions.

ENDNOTE

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Exhibit # 2 Pg 34 of 36

[REDACTED] DOB [REDACTED]

9-14-98
MONDAY
1530hrs.

Pt returned the call from this morning and she is doing better since friday...her headaches are subsided and she feels fatigue , which I told her is normal for starting vasotec BP med...it will pass as your body acclimates to the pills....

PLAN. pt to have thyroid scan on wed in [REDACTED]
pt to s-e me inoffice on friday am for bp recheck and
to discuss labs and ½t shld stard SYNTHROID
as directed after thryoid scan is completed.

Call if any questions and
continue low salt and fat diet.
END note.

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[REDACTED]
3/26/99 HRB

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Exhibit # 2 Pg 33 of 36

9-16-98

BP ✓

$\frac{170}{108}$ (R)

45 Y/6 ♀

Pt given note for no work this date for ~~the~~ then next four days.

counseled on effects of bp medsna to restat home and start taking the synthroid today.....

Call if any questions.

RECKEKC on friday. 9-18-98

Nonmedc 5 y t/d

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Exhibit # 2 Pg 32 of 36

NAME [REDACTED] AGE 45 yo

ADDRESS [REDACTED] DATE 9-16-98

Rx

NO WORK FOR THE NEXT ~~FOR~~ FOUR DAYS
9-16-98 to and including 9-20-98

THANK YOU VERY MUCH.

☐ LABEL

REFILL 0 1 2 3 4 5

☐ MAY SUBSTITUTE

☐ MAY NOT SUBSTITUTE

Generic Substitution Permitted

[REDACTED] M.D.

MD Dispense as Written

PT AUTHORIZED THIS FORM TO BE FAXED TO HER PLACE OF
EMPLOYMENT THIS DATE.

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Exhibit # 2 Pg 31 of 36

9-18-98

45 1/6 ♀ NKDA
Follow-up.

WT. 254 T. 97.6

P. 80

R. 16

BP 148/100 (R)

LAST wk in OCT draw thyroid Panel

BP

145 / 98 RT by Physician.

Pt feeling better and no headaches noted but still feels slightly tired and fatigued...i explained that this is secondary to the norvasc pills acclimating to her system...thsi css could resolve over time.....if it does note weii will change the pikl.

HEENT. Neck supple PERLA NEG NODES. NEG JVD or bruits.

Hrr c grade 1/2 /6 SEM neg clicks rubs or heaves.

Lungs CAT Neg rrw.

THYROID SCAN results of Wdd reveal No cold nodules and slightly enlarged RT side gland.

Extreme: neg edema.

Pulses 2/4 bilat upper and lower extremities.

- A: 1. Hypothyroidism new onset
2. Hypertension
3. Obesity.

PLAN. Continue norvasc 10mg per day in divided doses and will recheck bp in 2 weeks and pt to take bp daily and record....for charts in charts.

Call if any questions.

Will repeat [redacted] weeks. Oct 26th at [redacted]

END NOTE

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MEDICAL HISTORY

Name [redacted] Date: 9/18/98
Address [redacted] Age 45 Birthdate [redacted]
Sex: ☐ Male ☒ Female
Home Phone [redacted]
Work Phone [redacted]
Emergency Contact [redacted]
Phone [redacted]
Occupation Cashier
☐ Single ☐ Married ☒ Divorced ☐ Widowed ☐ Separated

If married, spouse's name N/A
Children's names and ages [redacted]

ALLERGIES TO MEDICATIONS, X-RAY DYES, OR OTHER SUBSTANCES ☒ No ☐ Yes
(If yes, please list name of medicine and type of reaction):
[redacted]
[redacted]
[redacted]
[redacted]

PAST MEDICAL HISTORY AND REVIEW OF SYSTEMS

Please circle if you have had problems with or are presently complaining of any of the following:

<u>High Blood Pressure</u>	Pneumonia	Unexplained weight loss/gain	Skin diseases
Diabetes	Persistent Cough	Hemorrhoids	Blood disorders
Cancer	T.B.	<u>Gall bladder disease</u>	Venereal diseases
<u>Heart Disease</u> <u>Murmur</u>	Hay Fever	Colitis	Anxiety
Chest Pain / Tightness	Abdominal Discomfort	<u>Hepatitis</u> or jaundice	Depression
Shortness of Breath	Indigestion	<u>Thyroid disease</u>	Anemia
Swollen Ankles	Nausea	Head or Neck radiation	Alcohol abuse
Palpitations	Vomiting	Headache	Drug abuse
Lightheadedness	Constipation	Kidney diseases	Gout
Frequent Urination	Diarrhea	Kidney stones	Blood transfusions
Rheumatic Fever	Blood in Stool	Difficulty urinating	
Asthma	Ulcers	Arthritis	
Bronchitis	Change in bowel habits	Low back problems	

Have you ever been hospitalized (If yes, give reason, date, and hospital): yes - High Blood Pressure / Thyroid
9/9/98 ; Gall Bladder - 8/86

Operations: Tonsillectomy - 76 ; Cyst Removal (Vaginal) - 75 ; Gall Bladder / Appendectomy - 86 ; Total Hysterectomy - 1990 ; Planter fasciitis - both feet 1998

GYNECOLOGIC AND OBSTETRIC HISTORY

ILMP 1990 Last Pap 8/98 Last Mammogram 9/98 Last Breast Exam 8/98
Age at onset of periods 13 Frequency monthly Length of period 5 days
IPregnancies 2 Births 1 Miscarriages 1 Method of Birth Control Hysterectomy
IProlonged or abnormal bleeding: ☒ No ☐ Yes Please describe:
ILeakage of urine: ☒ No ☐ Yes Adverse Event Project # 13167
IPelvic Pain: ☒ No ☐ Yes 3/26/99 HRB
IAbnormal Discharge: ☒ No ☐ Yes 000007
IHistory of abnormal Pap Smear: ☒ No ☐ Yes
IDo you do self breast exams? ☐ No ☒ Yes Exhibit # 2 Pg 1 of 34

PLEASE LIST AND SUPPLY THE DATA OF:

Immunization History - Have You Had:		Pneumovax immunization? <input type="checkbox"/> No <input type="checkbox"/> Yes When? _____
Hepatitis B?	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes When? <u>1993</u>	Flu immunization? <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes When? <u>1993</u>
Other?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes When? _____	Tetanus immunization? <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes When? <u>?</u>

When was your last:

Cholesterol Check: 8/98 Stool Check for blood: 8/98 ? Prostate Exam: _____

FAMILY HISTORY

Has any member of your family (including parents, grandparents, and siblings) every had the following?

Illness	Which Family Members?	Apprx. Age when Diagnosed
Cancer (describe type) <u>colon / liver</u>	<u>father (colon) mother (liver)</u>	<u>73 / 65</u>
Thyroid disorder	<u>sister</u>	<u>?</u>
Hypertension (high blood pressure)	<u>brother</u>	<u>90</u>
Heart Disease	<u>brother</u>	<u>92</u>
Diabetes	<u>uncle</u>	<u>?</u>
Strokes	<u>brother</u>	<u>92</u>
Mental disease (anxiety, depression, etc.)		
Drug or alcohol addiction		
Glaucoma	<u>1/2 sister</u>	<u>90</u>
Bleeding diseases (hemophilia, leukemia, etc.)		
Other:		

MEDICATIONS (PRESCRIPTIONS, OVER-THE-COUNTER, VITAMINS, HERBS, ETC.)

Drug Name	Dose	Drug Name	Dose

PREVENTION (Optional)

Do you wear seatbelts?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	If no, why not? _____
Do you wear a bike helmet?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> NA
Do you smoke?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	If yes, how many packs per day? _____
Do you drink alcoholic beverages?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	If yes, how much per week? _____
Do you drink coffee? <u>coke (has switched to caffeine free)</u>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	If yes, how many cups per day? _____
Do you drink tea?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	If yes, how many cups per day? _____
If there is a gun in your home, is it out of children's reach & unloaded?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA
Do you use drugs? (marijuana, cocaine, crack, etc.)	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	If yes, explain: _____
Have you ever engaged in any activity which put you at risk of AIDS?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	If yes, explain: _____
Do you wish to be tested for AIDS?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
Have you every worked with chemicals, paints, asbestos, or other hazardous material?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	If yes, explain: <u>battery company</u>
Are you in a relationship in which you have been physically hurt (e.g. slapped, kicked, punched, bruised) by your partner?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
Do you ever feel afraid of your partner?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
Do you have a "living will"?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
Do you have a donor card?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	

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Exhibit # 2 Pg 2 of 36

10-21-98

45 y/o ♀ NKDA
BP ✓

C/o feeling tired

WT 253

T 97.4

P 72

R 16

BP 118/78 (L)

Brother & arthritis

HTN

Hypothyroidism

At hip pain

Pt presents today with good spirits and feeling a little tired from the meds and is still acclimating to the new bp mds.....night job still a bit of a problem with sleeping in the day time. daily bp's are getting closer to nml and elevated bp's are not present anymore. Pr feels better and is eating well and watching her diet and taking her synthroid meds as directed.

VS as above. WNL. Stable.

Hent: Neck supple PERLA EO I sclera white. Fundi WNL.

Neg jvd or bruits. Thyroid not enlarged. neg nodules.

Hrr smurmurs eng w3 s4 clicks rubs or heaves.

Lungs CTA Negrrw.

Abd sft Bs allquads no masses or bruits. Neg rebound or guarding.

Auro: cn 2- 12 grossly intact, Nml gait and dtr's 2/4 bilat.

Psych: god spirits and mood good. pleasant and please with bp m, dms her progress.

A; 1. Hypothyroidism

2. Hyptn

3. ~~Obesity~~ Obesity, n

LAN: 1. RTC in one omnth for bp recheck and will check thyroid.

2. stay on [redacted] if any q#stions.

END NOTE.

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Exhibit # 2 Pg 3 of 36

[REDACTED]

NAME [REDACTED] AGE 45
ADDRESS [REDACTED] DATE 10-21-98

Rx Synthroid 0.1 mg
Disp # 60
Sig: $\dot{\bar{t}}$ / day

☐ LABEL
REFILL 0 1 2 3 4 5
☐ MAY SUBSTITUTE
☐ MAY NOT SUBSTITUTE
Generic Substitution Permitted [REDACTED] M.D.
M.D. Dispense as Written

[REDACTED]

NAME [REDACTED] AGE 45
ADDRESS [REDACTED] DATE 10-21-98

Rx Motrin 800 mg
Disp # 30
Sig: $\dot{\bar{t}}$ Po TID c Food

☐ LABEL
REFILL 0 1 2 3 4 5
☐ MAY SUBSTITUTE
☐ MAY NOT SUBSTITUTE
Generic Substitution Permitted [REDACTED] M.D.
M.D. Dispense as Written

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000010

Exhibit # 2 Pg 35 of 36

NAME

AGE

45

ADDRESS

DATE

10-21-98

Rx

No news 5 mg

Disp # 60

Sig: T PO Bid

☐ LABEL

REFILL 0 1 2 3 4 5

☐ MAY SUBSTITUTE☐ MAY NOT SUBSTITUTE

Generic Substitution Permitted

M D

M D Dispense as Written

TELEPHONE

NAME

AGE

45

ADDRESS

DATE

10-21-98

Rx

X Ray => Both hip

Dig: Antln Tis, Neurological
Pain☐ LABEL

REFILL 0 1 2 3 4 5

☐ MAY SUBSTITUTE☐ MAY NOT SUBSTITUTE

Generic Substitution Permitted

M D.

M D Dispense as Written

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Exhibit # 2 Pg 8 of 34

000011

[REDACTED]

NAME [REDACTED] AGE [REDACTED]
ADDRESS [REDACTED] DATE 10-27-98
Rx ILLEGAL IF NOT SAFETY BLUE BACKGROUND

Rx T3 T4 TSH please.

DIAG: Hypothyroidism.
244.9

[REDACTED] Refill _____ times
☐ Label

(Signature)
[REDACTED]

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000012

9-29-98

9/20 146/99 -

9/21 152/115

9/22 157/147

9/23

9/24 147/91 - P 82

9/25 156/99 P-81

9/26 155/100

9/27 150/98 - P 81

9/28 168/106 P-99

9/29 188/103 P-77

9/30

10/1

166/113 79
148
96

9-29-98 PT in for BP ✓ see above - [REDACTED]
1440

10-30-98 PT calls requesting lab & X-ray
1200 results. TSH not in lgt. X Ray hips
are normal. Discussed same w pt. [REDACTED]

11-3-98 OK lab letter to pt. Repeat Thyroid panel
in 3 months. per Dr. [REDACTED]

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160 Tues AM. 65
102

155 Tues P.M.
87

162 Wed P.M. 66
95

157 Thurs. P.M. 17
88

OH Nurse [redacted]

230
220
210
200
190
180
170
160
150
140
130
120
110
100
90
80
70
60



Adverse Event Project # 1316/
[redacted]
3/26/99 HRB

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9/15
9/16
9/17
9/18
9/19
9/20
9/21
9/22
9/23
9/24
9/25
9/26
9/27
9/28
9/29
9/30
9/31

10-21

Systolic
Diastolic

PROBLEM LIST

NAME: [REDACTED]

FPC#: 0003 [REDACTED]

UVA #:

#	Code #	MAJOR PROBLEMS	Date Enter	Date Res	#	Code #	EPISODIC PROBLEMS
1	[REDACTED]	HEALTH MAINTENANCE			1		
2	[REDACTED]	HTN			2		
3	[REDACTED]	Hypothyroidism			3		
4		S/p Hysterectomy 90			4		
5		S/p Colectomy & Appendectomy 86			5		
6		S/p plantar fasciitis Bilat 98			6		
7		S/p Tonsilectomy 76			7		
8	[REDACTED]	Obesity. morbid.			8		
9					9		
10					10		
11					11		
12					12		
13					13		
14					14		
15					15		
16					16		
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					31		
					32		

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X-RAY REPORT

PATIENT NAME: [REDACTED]
HOSPITAL NUMBER: [REDACTED]
DATE OF BIRTH: [REDACTED]
DATE OF X-RAY: 9-15/9-16-98
X-RAY NUMBER: [REDACTED]
ATTENDING PHYSICIAN: DR. [REDACTED]

CLINICAL DIAGNOSIS AND/OR PERTINENT HISTORY: HYPERTENSION, HEADACHE.

THYROID UPTAKE AND SCAN

392.6 microcuries of I-123 was given. The 24 hour uptake is 39%. Images of the thyroid were obtained. There are no cold nodules. There is slight increased activity over the right lobe compared to the left. The right lobe is larger.

IMPRESSION: 24 HOUR UPTAKE 39%. LARGER RIGHT LOBE THAN THE LEFT WITH SLIGHT INCREASED ACTIVITY OVER THE RIGHT LOBE COMPARED TO THE LEFT. NO COLD NODULES.

[REDACTED] M.D.

[REDACTED]
DET: 9-16-98



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[REDACTED]

RADIOLOGY REPORT

PATIENT NAME: [REDACTED]
PATIENT NUMBER: [REDACTED]

DATE OF STUDY: 10-28-98

ATTENDING PHYSICIAN: [REDACTED] MD

PELVIS/BILATERAL HIPS

Both hips are intact and in good position. No fractures are seen. There is no significant joint space narrowing in either hip. The bones are well mineralized. The visualized portions of the pelvis are unremarkable. There is no lytic or blastic lesion.

IMPRESSION: No significant abnormality identified.

[REDACTED] [REDACTED] MD

D: 10-28-98
T: 10-28-98

[REDACTED]



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[REDACTED]
3/26/99 HRB

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LAB REQUEST / REPORT

NURSE'S INITIAL	DATE	DESIRED TIME	AM PM
TECH'S INITIALS	DATE	COLLECTED TIME	AM PM
TECH'S INITIALS	DATE	COMPLETED TIME	AM PM

STAT ASAP	OUT PATIENT	PRE-OP	PNWHH
	GAP	HOSPICE	FA HC

X	TEST	RESULTS	UNITS	NORMAL
PROFILES				
	CBC & AUTO DIFF	SEE REPORT		
	CHEM-7	SEE REPORT		
	ELECTROLYTES	SEE REPORT		
	BCP - 21	SEE REPORT		
	CARDIAC PROFILE (CPK, LDH, SGOT) IF CK > 120 PERFORM CK-MB	SEE REPORT		
	LIVER FUNCTION (BCP-21 & SGPT)	SEE REPORT		
	ANEMIA PROFILE	SEE REPORT		
	LIPID PROFILE	SEE REPORT		
	TIBC	SEE REPORT		

HEMATOLOGY / COAG.				
	BLEEDING TIME	MIN		3-9
	HEMOGLOBIN (HGB)	GM/100ML		11.3-15.5
	HEMATOCRIT (HCT)	%		32.4-45.4
	RETIC COUNT	%		0.5-2.7
	MANUAL DIFF			
	SED RATE (ESR) (WEST)	MM/HR		F 0-20 M 0-15
	APTT	SEC.		21-35
	PROTIME	SEC.		10.8-12.8
	THERA. INDEX			
	INR			

CHEMISTRY				
	ACETONE SERUM (KETONE)	SEE REPORT		NEG.
	ALBUMIN	G/dL		3.9-5.0
	ALCOHOL (MEDICAL)	MG/dL		TOXIC > 200
	ALCOHOL (LEGAL)	GIVE BLOOD TO POLICE		
	DRUG & ALCOHOL KIT (LEGAL)			
	ALKALINE PHOS	U/L		38-126
	AMMONIA	UMOL/L		9-33
	AMYLASE	U/L		30-110
	ANA	SEE REPORT		
	B-12	SEE REPORT		
	BETA - HCG (QUANTITATIVE)	mIU/ML	< 10 NON-PREGNANT	
	BILIRUBIN (TOTAL)	MG/dL		0.2-1.0
	BUN	MG/dL		7-18
	CALCIUM	MG/dL		8.4-10.2
	CEA	NG/ML		< 5.0
	CELL COUNT (BODY FLUID)	SEE COMMENTS		
	CHOLESTEROL	MG/dL		139-200
	CLO TEST			NEGATIVE
	CPK (CK)	U/L		30-170
	CK-MB	NG/ML		< 5.0
	CORTISOL	SEE REPORT		

X	TEST	RESULTS	UNITS	NORMAL
	CREATININE		MG/dL	0.7-1.5
	CREATININE CLEARANCE	SEE REPORT		
	DIGOXIN	SEE REPORT	NG/ML	0.8-2.0
	DILANTIN	SEE REPORT	UG/ML	10-20
	DRUG SCREEN	SEE REPORT		
	FERRITIN		NG/ML	F 10-120 M 20-300
	FOLATE (FOLIC ACID)	SEE REPORT		
	GENTAMYCIN		UG/ML	TROUGH 1-2 PEAK 5-10
	GLUCOSE		MG/dL	65-110
	HGB A1C (GLYCOHEMOGLOBIN)		%	4.2-6.3
	HIV HTLV-III	SEE REPORT		
	LDH		U/L	313-618
	LDH ISO ENZYMES	SEE REPORT		
	LEAD			
	LIPASE		U/L	23-300
	LITHIUM	SEE REPORT		
	MAGNESIUM		MG/dL	1.7-2.2
	MYOGLOBIN		NG/ML	F 12-76 M 19-92
	PHENOBARBITAL		UG/ML	15-40
	PHLEBOTOMY (THERAPEUTIC)	ML DRAWN =		
	PHOSPHORUS		MG/dL	2.5-4.5
	PKU			
	POTASSIUM		mmol/L	3.6-5.0
	PROCAINAMIDE	SEE REPORT		
	PROLACTIN	SEE REPORT		
	PROTEIN, TOTAL		G/dL	6.3-8.2
	PSA	SEE REPORT		
	QUINIDINE		MG/L	2.0-5.0
	SALICYLATES		MG/L	50-100
	SEMEN ANALYSIS (COMPLETE)	SEE COMMENTS		
	SEMEN ANALYSIS (POST SURGERY)	SEE COMMENTS		
	SGOT (AST)	SEE REPORT	U/L	5-40
	SGPT (ALT)	SEE REPORT	U/L	7-56
	SODIUM	SEE REPORT	mmol/L	137-145
	SURG. SPEC. HANDLING FEE			
	T UPTAKE	45	%	25-37
	T4	12.3	UG/dL	4.4-12.2
	THYROXINE INDEX	3.1		1.2-3.4
	TSH	4.0	mIU/L	0.4-4.2
	TEGRETOL		UG/ML	8.0-12.0
	THEOPHYLLINE		UG/ML	10-20
	TRIGLYCERIDES		MG/dL	35-160

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X	TEST	RESULTS	UNITS	NORMAL
	VALPORIC ACID (DEPAKOT)		UG/ML	50-100
	VANCOMYCIN		UG/ML	THROUGH 5-10 PEAK 20-40
EKG				
SEROLOGY				
	PREGNANCY TEST (SERUM)			
	PREGNANCY TEST (URINE)			
	MONO TEST			NEGATIVE
	RPR			NON-REACTIVE < 0.5 NEG > 1.0 POS
	RUBELLA SCREEN			
	STREP SCREEN			
BACTERIOLOGY				
	SOURCE			
	BACTERIAL CULTURE	SEE REPORT		
	BLOOD CULTURE	SEE REPORT		
	CHLAMYDIA/GC GEN PROBE	SEE REPORT		
	GRAM STAIN	SEE COMMENTS		
STOOL				
	C DIFFICILE TOXIN			NEGATIVE
	CULTURE	SEE REPORT		
	GIARDIA ANTIGEN			NEGATIVE
	OCCULT BLOOD			NEGATIVE
	OVA & PARASITE	SEE REPORT		
	WBC			NONE SEEN

MISC. TEST & COMMENTS

RECEIVED

BILLS

BILLED BY SK

000018